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August 28, 2003

\*ADMITTED TO D.C. BAR, D.C. PRACTICE OF  
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AND AGENCIES

Commissioner of Patents  
U.S. Patent and Trademark Office  
2011 South Clark Place  
Customer Window  
Crystal Plaza Two, Lobby, Room 1B03  
Arlington, VA 22202  
Assistant Commissioner for Patents  
Washington, DC 20231

Re: Second Supplemental Information Disclosure Statement  
Appl. No.: 09/993,959  
Filed: November 27, 2001  
Title: **Method of Treating Rhinitis or Sinusitis**  
Inventor(s): Grouzmann, *et al.*  
Atty. Dkt.: 7571/73191 (formerly 81985/282428)

Dear Sir:

The following documents are being forwarded herewith for appropriate action by the U.S. Patent and Trademark Office:

1. Second Supplemental Information Disclosure Statement;
2. Form PTO-1449, List of References Cited by Applicant;
3. References AA1-AB2, AH1-AI3, and AI1-AP4; and
4. One return postcard.

Commissioner of Patents  
August 28, 2003  
Page 2

**The Commissioner is hereby authorized to charge the fee for filing an IDS in the amount of \$180.00 to our Deposit Account No. 06-1135 under Order No. 7571/73191. The Commissioner is also hereby authorized to charge any fee deficiency or credit any overpayment to our Deposit Account No. 06-1135 under Order No. 7571/73191.**

It is respectfully requested that the enclosed postcard be stamped with the date the enclosed documents are received by the PTO and that it be returned as soon as possible.

Very truly yours,

FITCH FVEN, TABIN & FLANNERY

A handwritten signature in cursive script that reads "Michael A. Sanzo".

Michael A. Sanzo  
Reg. No. 36,912  
Attorney for Applicants

MAS:ct  
Enclosures



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:

Grouzmann, *et al.*

Appl. No.: 09/993,959

Filed: November 27, 2001

For: **Method of Treating Rhinitis or Sinusitis**



Art Unit: 1654

Examiner: M. Meller

Atty. Dkt.: 7571/73191  
(Formerly 81985/282428)

**Second Supplemental Information Disclosure Statement**

Commissioner of Patents  
U.S. Patent and Trademark Office  
2011 South Clark Place  
Customer Window  
Crystal Plaza Two, Lobby, Room 1B03  
Arlington, VA 22202

Sir:

Submitted herewith is a listing of documents known to Applicants and/or their attorney in compliance with the requirements of 37 C.F.R. § 1.56. Copies of the listed documents are also enclosed.

Applicants also wish to make the Examiner aware of co-pending application 09/897,433, filed July 3, 2001.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned attorney submits the following concise explanation of the relevance of the non-English language document cited on the accompanying form:

Reference AJ1, PCT published application WO 93/09116, describes quinuclidine derivatives that act as substance P antagonists. The derivatives can be used to treat pain and disorders of the respiratory, CNS, cardiovascular and digestive systems. An English language

abstract corresponding to this document is enclosed herewith and is cited on the accompanying list of references as document AO4.

Reference AH3, European patent document EP 0 514 274, describes perhydroisoindole derivatives used as intermediates for substance P antagonists. An English language abstract corresponding to this document is enclosed herewith and is cited on the accompanying list of references as document AP4.

Applicants do not waive any rights to appropriate action to establish patentability over any of the listed documents should they be applied as references against the claims of the present application. This statement should not be construed as a representation that more material information does not exist or that an exhaustive search of the relevant art has been made.

Consideration of the cited documents and making the same of record in the prosecution of the above-captioned application are respectfully requested.

The Commissioner is hereby authorized to charge the fee for the filing of this Information Disclosure Statement to our Deposit Account No. 06-1135 under Order No. 7571/73191.


Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

By Michael A. Sanzo  
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Reg. No. 36,912  
Attorney for Applicants

Date August 28, 2003  
1801 K Street, N.W., Suite 401L  
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Phone: (202) 419-7013

LIST OF REFERENCES CITED BY APPLICANT <small>(on several sheets if necessary)</small>				Atty. Docket No. 7571 73191		Appl. No. 09 993,959	
				Applicant(s) Grouzmann, <i>et al</i>			
				Filing Date: November 27, 2001		Group 1654	



U.S. PATENT DOCUMENTS								
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate	
	AA 1	4,472,305	Sep. 18, 1984	Hansen, <i>et al</i>	260	112.5	May 17, 1983	
	AB 1	4,680,283	Jul. 14, 1987	Veber, <i>et al</i>	514	17	Aug. 20, 1986	
	AC 1	4,839,465	Jun. 13, 1989	Singh, <i>et al</i>	530	330	Jan. 20, 1987	
	AD 1	5,508,433	Apr. 16, 1996	Achard, <i>et al</i>	548	515	Nov. 17, 1993	
	AE 1	5,795,574	Aug. 18, 1998	Breton, <i>et al</i>	424	195.1	Sep. 9, 1996	
	AF 1	6,063,758	May 16, 2000	Lappi, <i>et al</i>	514	2	Jul. 9, 1997	
	AG 1	6,146,636	Nov. 14, 2000	Breton, <i>et al</i>	424	195.1	Sep. 22, 1998	
FOREIGN PATENT DOCUMENTS								
		Document Number	Date	Country	Class	Subclass	Abstract	
							Yes	No
	AH 1	WO 93/01165	21 January 1993	WIPO	C07C	271/16		
	AI 1	WO 93/01169	21 January 1993	WIPO	C07D	209/14		
	AJ 1	WO 93/09116	13 May 1993	WIPO	C07D	453/02	X	
	AK 1	WO 99/47152	23 September 1999	WIPO	A61K	38/00		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)								
	AL 1	Abdel-Ghany, <i>et al</i> , "Truncated Dipeptidyl Peptidase IV Is a Potent Anti-Adhesion and Anti-Metastasis Peptide for Rat Breast Cancer Cells," <i>Invasion Metastasis</i> 18:35-43 (1998).						
	AM 1	Bou-Gharios, <i>et al</i> , "Expression of Exopeptidases in Scleroderma," <i>Ann Rheum Diseases</i> 54:111-116 (1995).						
	AN 1	Elgün, <i>et al</i> , "Dipeptidyl Peptidase IV and Adenosine Deaminase Activity Decrease in Depression," <i>Psychoneuroendocrinology</i> 24:823-832 (1999).						
	AO 1	Grönblad, <i>et al</i> , "Neuropeptides in Synovium of Patients with Rheumatoid Arthritis and Osteoarthritis," <i>J. Rheumatol</i> 15:1807, 1810 (1988).						
	AP 1	Hamel, <i>et al</i> , "Tachykinin Involvement in Cutaneous Anaphylaxis in the Guinea Pig," <i>Can J Physiol Pharmacol</i> 66:1361-1367 (1988).						
	AQ 1	Heins, <i>et al</i> , <i>Biochim Biophys Acta</i> 785:30-35 (1984) Abstract.						
Examiner				Date Considered				

LIST OF REFERENCES CITED BY APPLICANT  
(Use several sheets if necessary)



Atty. Decker No. 7571 73191

Appl. No. 09 993,959

Applicant(s) Grouzmann, *et al*

Filing Date: November 27, 2001

Group 1654

U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	AA 2	6,166,063	Dec. 26, 2000	Villhauer	514	423	Dec. 9, 1999
	AB 2	6,325,989 B1	Dec. 4, 2001	Duke-Cohan, <i>et al</i>	424	9.34	Jun. 1, 1995
	AC						
	AD						
	AE						
	AF						
	AG						

FOREIGN PATENT DOCUMENTS


		Document Number	Date	Country	Class	Subclass	Abstract	
							Yes	No
	AH 2	WO 02/31134	18 April 2002	WIPO	C12N	9/64		
	AI 2	EP 0 394 989	31 October 1990	EPO	C07K	5.00		
	AJ 2	EP 0 436 334	10 July 1991	EPO	C07D	207/14		
	AK 2	EP 0 499 313	19 August 1992	EPO	C07D	453.02		

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AL 2	Hildebrandt, <i>et al</i> , "A Guardian Angel: The Involvement of Dipeptidyl Peptidase IV in Psychoneuroendocrine Function, Nutrition and Immune Defense," <i>Clin. Sci.</i> 99:93-104 (2000).
	AM 2	Kimball, <i>et al</i> , "Substance P, Neurokinin A, and Neurokinin B Induce Generation of IL-1-Like Activity in P388D1 Cells," <i>J. Immunol.</i> 141 3564-3569 (1988).
	AN 2	Langdon, <i>et al</i> , "Broad Spectrum Neuropeptide Antagonists Inhibit the Growth of Small Cell Lung Cancer <i>in Vivo</i> ," <i>Cancer Res.</i> 52:4554-4557 (1992).
	AO 2	Levine, <i>et al</i> , "Intraneuronal Substance P Contributes to the Severity of Experimental Arthritis," <i>Science</i> 226:547-549 (1984).
	AP 2	Lotz, <i>et al</i> , "Effect of Neuropeptides on Production of Inflammatory Cytokines by Human Monocytes," <i>Science</i> 241:1218-1221 (1988).
	AQ 2	Maggi, <i>et al</i> , "Tachykinin Receptors and Tachykinin Receptor Antagonists," <i>J. Auton. Pharmacol.</i> 13:23-93 (1993).

Examiner	Date Considered
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<b>LIST OF REFERENCES CITED BY APPLICANT</b> <small>(Use separate sheets, if necessary)</small>				Atty. Docket No. 7571 73191		Appl No 09 993,959	
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				Filing Date, November 27, 2001		Group 1654	



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	AA						
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	AF						
	AG						

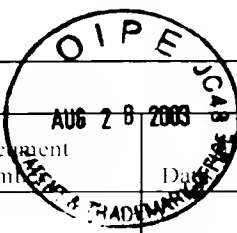
FOREIGN PATENT DOCUMENTS								
		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
	AI 3	EP 0 514 274	19 November 1992	EPO	C07D	209 44	X	
	AI 3	EP 0 522 808	13 January 1993	EPO	C07C	217 48		
	AJ							
	AK							

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)		
	AL 3	Mantyh, <i>et al.</i> , "Receptor Binding Sites for Substance P and Substance K in the Canine Gastrointestinal Tract and Their Possible Role in Inflammatory Bowel Disease," <i>Neuroscience</i> 25:817-837 (1988).
	AM3	Mantyh, <i>et al.</i> , "Receptor Binding Sites for Substance P, But Not Substance K or Neuromedin K, Are Expressed in High Concentrations by Arterioles, Venules, and Lymph Nodules in Surgical Specimens Obtained from Patients with Ulcerative Colitis and Crohn Disease," <i>Proc Natl Acad Sci USA</i> 85:3235-3239 (1988).
	AN 3	Otsuka, <i>et al.</i> , "Role of Substance P As a Sensory Transmitter in Spinal Cord and Sympathetic Ganglia," <i>Ciba Foundation Symposium</i> 91:13-34 (1982).
	AO3	Otsuka, <i>et al.</i> , "Does Substance P Act As a Pain Transmitter?" <i>TIPS</i> 8:506-510 (1987).
	AP 3	Sandberg, <i>et al.</i> , "Substance P," <i>J Med Chem</i> 25:1009-1015 (1982).
	AQ 3	Ianaka, <i>et al.</i> , "Anti-Arthritic Effects of the Novel Depeptidyl Peptidase IV Inhibitors TMC-2A and TSI-225," <i>Immunopharmacology</i> 40:21-26 (1998) Abstract.

Examiner	Date Considered
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<b>LIST OF REFERENCES CITED BY APPLICANT</b> <i>(Use several sheets if necessary)</i>				Atty. Docket No. 7571 73191		Appl. No. 09 993,959	
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	AA						
	AB						
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FOREIGN PATENT DOCUMENTS								
		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
	AH							
	AI							
	AJ							
	AK							

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)	
	AL 4 Tanaka, <i>et al.</i> "Suppression of Arthritis by the Inhibitors of Depeptidyl Peptidase IV," <i>Intl. J. Immunopharmacology</i> 19:15-24 (1997) Abstract.
	AM4 Tattersall, <i>et al.</i> , "The Tachykinin NK Receptor Antagonist CP-99,994 Attenuates Cisplatin Induced Emesis in the Ferret," <i>Eur. J. Pharmacol.</i> 250:R5-R6 (1993).
	AN 4 Yankner, <i>et al.</i> , "Neurotrophic and Neurotoxic Effects of Amyloid $\beta$ Protein: Reversal by Tachykinin Neuropeptides," <i>Science</i> 250:279-282 (1990).
	AO4 Abstract for WO 93 09116. Reference AH above.
	AP 4 Abstract for EP 0 514 274. Reference AH3 above.
	AQ

Examiner	Date Considered
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